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MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			STAPLES, MARK	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/508,799

**Applicant(s)**

JOHANSEN, JACK T

**Examiner**

Mark Staples

**Art Unit**

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>09/21/2004</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Specification***

2. Priority to the provisional application 60,367,060 should be stated in the first paragraph of the specification.

3. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: (1) "An 18-mer fully phosphorothioated deoxyribonucleotide containing 66% full length product" and (2) "was purified 5'-dimethoxytrityl on using the method" found in the 1<sup>st</sup> paragraph under Example 3 on page 15. "An 18-mer fully phosphorothioated deoxyribonucleotide" is a full length product, there is no degree or percentage involved. The second construction is unclear grammar as well.

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4. The abstract of the disclosure is objected to because of legal phraseology in use of the words "thereon" and "thereby". Correction is required. See MPEP § 608.01(b).

5. The use of the trademark SEPHAROSE has been noted in this application. It and any other trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Objections***

6. Claim 8 is objected to because of the following informalities: there is an unnecessary period after the word "claim" in line 1. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, 13, 22, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially free of" in claims 4 and 27 is a relative term which renders the claim indefinite. The term "substantially free of" is not defined by the claim,

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the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This term is applied to metal salts and one of ordinary skill in the would not know what level of metal salts is permissible. Examiner notes that this term is discussed in the specification in lines 4-7 on page 12. However, the discussion found there does not provide a standard for ascertaining the requisite degree of this term.

The term "substantially increase" in claims 5 and 27 is a relative term which renders the claim indefinite. The term "substantially increase" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This term is applied to salt concentration and one of ordinary skill in the would not know what level of salt increase is permissible. Examiner notes that this term is discussed in the specification in lines 34-36 on page 12. However, the discussion found there does not provide a standard for ascertaining the requisite degree of this term.

The term "sufficient amount" in claim 22 is a relative term which renders the claim indefinite. The term "sufficient amount" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This term is applied to an acidic solution and one of ordinary skill in the would not know what amount of an acidic solution is permissible. Examiner notes that this term is discussed in the specification in lines 25-28 on page 3. However, the

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discussion found there, while providing a concentration range for the example of one acid which is acetic acid, does not provide a standard for ascertaining the requisite degree of this term, which is the "amount" that is permissible.

The term "linear manner" in claim 13 is a relative term which renders the claim indefinite. The term "linear manner" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This term is applied to an increase in pH and one of ordinary skill in the art would not know what degree of linearity is permissible.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the solution in step 1b is increasing in pH with time. It is not recited and hence is indefinite as to how the solution is changing pH over time.

### ***Claim Rejections – 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 5-7, 10, 12-14, 16-18, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Lu et al. (1994), cited on the Information Disclosure Statement, IDS.

Regarding claim 1, Lu et al. teach a method of separating a target oligonucleotide from an impurity, in a mixture comprising said target oligonucleotide and said impurity, using a titratable anion exchange composition, comprising the steps:

- a) binding said target oligonucleotide to said titratable anion exchange composition;
- b) passing a solution through said titratable anion exchange composition with target oligonucleotide bound thereon, wherein said solution increases in pH over time (see Figure 1 for pH increase after 30 minutes); and
- c) eluting said target oligonucleotide, wherein said impurity elutes at a different pH than said target oligonucleotide (entire article, especially Table 1 and column "pH gradient<sup>d</sup>").

Regarding claim 5, Lu et al. teach a method with use of a pH gradient where salt concentration does not vary over time, that is, wherein the addition of solution B to solution A does not increase salt concentration over time (see p. 340, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph, 2<sup>nd</sup> sentence for the elution in pH gradient).

Regarding claim 6 and 7, Lu et al. teach a method wherein said titratable anion exchange composition is conjugated to a support which is a synthetic polyether resin (see section 2.1 Chemicals on p. 340 for the MONO Q HR column consisting of a quaternary amine resin and see supporting document of Kralj et al. (2003) p. 2, sentences 11 and 12 for polyether resin).

Regarding claim 10, Lu et al. teach a method wherein said target oligonucleotide is a synthetic oligonucleotide (see p. 340 section 2.1 Chemicals where mono and di-nucleotides were obtained from Sigma).

Regarding claim 12, Lu et al. teach a method wherein binding of said target oligonucleotide with said titratable anion exchange composition occurs at a pH between 5 and 8 (see Table 1 where peak 7 elutes at pH 8 and column pH gradient<sup>d</sup>).

Regarding claim 13, Lu et al. teach a method where a solution increases in pH in a linear manner over time (See Figure 1 for linear increases at 1 to 10 minutes and 33 to 37 minutes).

Regarding claim 14, Lu et al. teach a method wherein a solution increases from a pH of about 8 to a pH of about 8.5, which is a pH of about 11 (See Figure 1 from 33 to 37 minutes).

Regarding claim 16, Lu et al. teach a method wherein said target oligonucleotide has a length of 4 which is about 8 nucleotides (See Table 1).

Regarding claim 17, Lu et al. teach a method wherein said impurity is one or more oligonucleotides having a shorter length, peak 1 = d(AA), than said target oligonucleotide, peak 3 = d(AAT), and wherein said impurity elutes at a lower pH of about 10.4 than said target oligonucleotide elution pH of about 10.6.

Regarding claim 18, Lu et al. et al. teach a method wherein said impurity is one or more failure sequences (entire reference, especially Title Figure 1).



Regarding claim 25, Lu et al. teach a method with a washing step prior to eluting said target oligonucleotide, that is, pumping of a solvent to for about 20 minutes to restore the pH (see p. 340, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph, 6<sup>th</sup> sentence).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4, 8, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu at al. (1994) as applied to claims 1, 5-7, 10, 12-14, 16-18, and 25 above, and further in view of Asteriadis et al. (1976), cited on the IDS.

Lu at al. teach as noted above.

Lu et al. do not specifically teach a method of low salt, a styrene-divinyl benzene copolymer, or a solution of NH<sub>4</sub>OH.

Regarding claim 4, Asteriadis et al. teach a method wherein a solution is relatively of relatively low salt concentration, that is substantially free of metal salts and other salts (entire reference, especially p. 65, 2<sup>nd</sup> paragraph, 2<sup>nd</sup> sentence).

Regarding claim 8, Asteriadis et al. teach a method wherein said synthetic polymer is styrene-divinyl benzene copolymer (see page 65, section Materials for AG 1-X2 and AG 1-X4 and supporting document by BIO RAD p. 2, 1<sup>st</sup> sentence identifying the synte hic polymer as styrene-divinyl benzene copolymer).

Regarding claim 15, Asteriadis et al. teach a method using a solution of  $\text{NH}_4\text{OH}$  (see p. 67, 1<sup>st</sup> sentence).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Lu at al. by using a method of low salt, a styrene-divinyl benzene copolymer, or a solution of  $\text{NH}_4\text{OH}$  as suggested by Asteriadis et al. with a reasonable expectation of success. The motivation to do so is provided by Asteriadis et al., who teach the usefulness of a method of low salt, a styrene-divinyl benzene copolymer, or a solution of  $\text{NH}_4\text{OH}$  for purification of oligonucleotides and the teaching of Lu at al. for the separation of oligonucleotides. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

10. Claim 2, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu at al. (1994) as applied to claims 1, 5-7, 10, 12-14, 16-18, and 25 above, and further in view of Jin-Yan et al. (WO9527718 published in 1995), cited on the IDS.

Lu at al. teach as noted above.

Lu et al. do not specifically teach a tertiary amine, synthetic support polymer, or a synthetic oligonucleotide which is a phosphorothioate.

Regarding claim 2, Jin-Yan et al. teach a method wherein said titratable anion exchange composition comprises a tertiary amine, dimethylaminoethyl or DMAE (see p. 10, line 5).

Regarding claim 8, Jin-Yan et al. teach a method wherein said support is a synthetic polymer, the polyacrylic linked polymethacrylate resin which is the support for FRACTOGEL® EMD DMAE from Merck (see Merck datasheet for FRACTOGEL® EMD DMAE).

Regarding claim 11, Jin-Yan et al. teach a method using a synthetic oligonucleotide which is a phosphorothioate (entire reference, especially Title and Abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Lu at al. by using a tertiary amine, a synthetic polymer, and a phosphorothioate as suggested by Jin-Yan et al. with a reasonable expectation of success. The motivation to do so is provided by Jin-Yan et al. who teach the usefulness of a tertiary amine and a synthetic polymer for purifying oligonucleotides which are phosphorothioates and the teaching of Lu at al. for the separation of oligonucleotides. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

11. Claims 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu at al. (1994) as applied to claims 1, 5-7, 10, 12-14, 16-18, and 25 above, and further in view of Crane et al. (US Patent 5,092,992 issued 1992).

Lu at al. teach as noted above.

Lu et al. do not specifically teach polyethyleneimine-derivatized silica gel.

Regarding claims 3 and 9, Crane et al. polyethyleneimine-derivatized silica gel for affinity chromatography (entire reference, especially the Title).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Lu et al. by using polyethyleneimine-derivatized silica gel as suggested by Crane et al. with a reasonable expectation of success. The motivation to do so is provided by Crane et al. who teach the usefulness of and polyethyleneimine-derivatized silica gel in chromatography and the teaching of Lu et al. for the separation of oligonucleotides. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

12. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lu et al. (1994) as applied to claims 1, 5-7, 10, 12-14, 16-18, and 25 above and further in view of Beatty et al. (1999).

Lu et al. teach as noted above.

Lu et al. do not specifically teach a method the impurity is a metal salt.

Beatty et al. teach a method where the ion exchange composition "WP-1 [poly(ethyleneimine) (PEI)-silica composite material] exhibits better metal ion capture kinetics under rapid flow conditions and maintains its copper capacity and structural integrity better than the polystyrene based chelator resin IRC-718 . . ." (see 1<sup>st</sup> sentence of the section *Conclusion* on p. 4408).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Lu et al. by using poly(ethyleneimine)-silica to remove metal ions/salts using as suggested by Beatty et al. with a reasonable expectation of success. The motivation to do so is provided by Beatty et al. who teach the use ion exchangers to remove metal ions/salts and the teaching of and the teaching of Lu et al. for the separation of oligonucleotides. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

13. Claims 20-23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu et al. (1994) as applied to claims 1, 5-7, 10, 12-14, 16-18, and 25 above and further in view of Fruchtel et al. (1996).

Lu et al. teach as noted above.

Lu et al. do not specifically teach a method wherein a target oligonucleotide is 5'-O-protected, is 5'-O-trityl protected, where there is a sufficient amount of an acidic solution to cleave said 5'-O-trityl protecting group from a target oligonucleotide prior to elution, and where acidic solution comprises aqueous acetic acid.

Regarding claims 20 and 21, Fruchtel et al. where the target oligonucleotide is 5'-O-trityl protected (entire reference, especially p. 20 1<sup>st</sup> paragraph).

Regarding claims 22 and 23, Fruchtel et al. teach that acid condition cleave 5'-O-trityl protecting group including acetic acid (see 2<sup>nd</sup> sentence on page 20: "... the trityl anchoring bond can be cleaved by very weak acids such as acetic acid").

Regarding claim 26, Fruchtel et al. teach where the target oligonucleotide is is 5'-O-dimethoxy-trityl protected (entire reference, especially Scheme 41 on p 39 and footnote on page 17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Lu at al. by using a target oligonucleotide which is 5'-O-protected, which is 5'-O-trityl protected, where there is a sufficient amount of an acidic solution to cleave said 5'-O-trityl protecting group from a target oligonucleotide prior to elution, and where acidic solution comprises aqueous acetic acid; as suggested by Fruchtel et al. with a reasonable expectation of success. The motivation to do so is provided by Fruchtel et al. who teach the usefulness of a target oligonucleotide which is 5'-O-protected, which is 5'-O-trityl protected, where there is a sufficient amount of an acidic solution to cleave said 5'-O-trityl protecting group from a target oligonucleotide prior to elution, and where acidic solution comprises aqueous acetic acid; and the teaching of Lu at al. for the separation of oligonucleotides. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

14. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lu at al. (1994) as applied to claims 1, 5-7, 10, 12-14, 16-18, and 25 above and further in view of Ferreira et al. (2000).

Lu at al. teach as noted above.

Lu et al. do not specifically teach a method wherein anion exchange concentrate the target oligonucleotide.

In regards to claim 24, Ferreira et al. teach "AEC [Anion Exchange Chromatography] has been used as an initial purification step to capture and to concentrate plasmid DNA" (see p. 386, 2<sup>nd</sup> paragraph, 2<sup>nd</sup> sentence under the section *Strategies for purifying supercoiled plasmid DNA*).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Lu et al. using an anion exchange composition to concentrate a target oligonucleotide as suggested by Ferreira et al. with a reasonable expectation of success. The motivation to do so is provided by Ferreira et al. who teach the concentration of a target oligonucleotide, a target DNA plasmid, by AEC and the teaching and the teaching of Lu et al. for the separation of oligonucleotides. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

15. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lu et al. (1994) as applied to claims 1, 5-7, 10, 12-14, 16-18, and 25 above and further in view of Crane et al. (1992) and Asteriadis et al. (1976).

Lu et al. teach as noted above, and it is re-noted regarding claim 27 in part that Lu et al. teach a method wherein a solution increases from a pH of about 8 to a pH of about 8.5, which is a pH of about 11 (See Figure 1 from 33 to 37 minutes).

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Lu et al. do not specifically teach a method wherein a titratable anion exchange composition comprises polyethyleneimine, polyimidazole, polyhistidine or polylysine conjugated to a synthetic polymer support; a solution substantially free of metal salts, does not substantially increase its salt concentration over time, and comprises one or more of  $\text{NH}_4\text{HCO}_3$  and/or  $\text{NH}_4\text{OH}$ .

Regarding claim 27 in part, Crane et al. <sup>teach</sup> polyethyleneimine-derivatized silica gel for affinity chromatography (entire reference, especially the Title).

Regarding claim 27 in part, Asteriadis et al. teach a method wherein a solution is relatively of relatively low salt concentration, that is substantially free of metal salts and other salts (entire reference, especially p. 65, 2<sup>nd</sup> paragraph, 2<sup>nd</sup> sentence).

Regarding claim 27 in part, Asteriadis et al. teach a method using a solution of  $\text{NH}_4\text{OH}$  (see p. 67, 1<sup>st</sup> sentence).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teaching of Lu et al. by using a polyethyleneimine-derivatized silica gel, a solution is relatively of relatively low salt concentration, and a solution of  $\text{NH}_4\text{OH}$  as suggested by Crane et al. and Asteriadis et al. with a reasonable expectation of success. The motivation to do so is provided by Crane et al. and Asteriadis et al. who teach the usefulness of a polyethyleneimine-derivatized silica gel, a solution is relatively of relatively low salt concentration, and a solution of  $\text{NH}_4\text{OH}$  and the teaching of Lu et al. for the separation of oligonucleotides. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.



### ***Reference of Record***

Smith et al. (US Patent No. 6,806,362 filed March 20, 2001) is made of reference of record as being of interest in regards to the instant application. Smith et al. teach methods of making and using pH dependent ion exchange matrices.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10,159,322. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending

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Application No. 10,159,322 by Johansen et al. recite critical elements of compositions found in the claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

17. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples  
Examiner  
Art Unit 1637  
October 27, 2006

MS

*Kenneth R. Horlick*  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER  
10/30/06